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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,191	10/26/2006	Vega Masignani	PP020667.0003	4113

27476 7590 02/23/2009

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
02/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,191	MASIGNANI ET AL.	
	Examiner	Art Unit	
	VANESSA L. FORD	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 13-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10 and 13-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A preliminary amendment was filed December 22, 2005. The status of the claims are as follows: Claims 1, 4-6, 8 and 9-10 have been amended. Claims 14-23 have been added. Claims 11-12 have been canceled. Claims 1-10 and 13-23 are recited in the restriction requirement below.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I Claims 1–6, 10 and 18-19 are drawn to a polypeptide comprising one or more of (a) an amino acid sequence selected from the group consisting of SEQ ID NOs. 51, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 and 54; (b) an amino acid sequence having at least 70% identity to a sequence as defined in (a) and/or (c) an amino acid sequence comprising a fragment of at least 8 consecutive amino acids of a sequence as defined in (a) and pharmaceutical composition.

Group II	Claims 7 and 20 are drawn to an adhesion from *Haemphilis aeyptius*, wherein the adhesion comprises (a) amino acid sequence SEQ ID NO:52; (b) an amino acid sequence sequence having at least 70% identity to SEQ ID NO:52, and/or (c) an amino acid sequence which is a fragment of at least 8 consecutive amino acids of SEQ ID NO:52.
Group III	Claims 8 and 15 are drawn to an antibody and composition.
Group IV	Claims 9 and 16 are drawn to a nucleic acid encoding a polypeptide and pharmaceutical composition.
Group V	Claims 13 and 21-22 are drawn to a method for raising an immune response in a mammal comprising the step of administering an effective amount of the composition.
Group VI	claims 14 and 17 are drawn to a nucleic acid encoding an antibody.
Group VII	Claim 23 is drawn to a method for raising an immune response in a mammal comprising the step of administering an effective amount of the composition.

3. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature lacks novelty under PCT Article 33(2) as anticipated by Elkins which teaches a SSRA protein of *Haemphilus ducreyi* that is 100 % identical to SEQ ID No:6. See sequence alignment below:

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  Query Match             100.0%;  Score 1424;  DB 4;  Length 273;
  Best Local Similarity   100.0%;  Pred. No. 1.9e-129;
  Matches  273;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 MKIKCLVAVVGLACSTITTMAQQPPKFAGVSSLYSYEYDYGKGKWTWSNEGGFDIKVPGI 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MKIKCLVAVVGLACSTITTMAQQPPKFAGVSSLYSYEYDYGKGKWTWSNEGGFDIKVPGI 60

Qy         61 KMKPKEWISKQATYLELQHYMPYTPVLVTSAPDVSPSSISILLYPMSDPDQLGINRQQLK
120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 KMKPKEWISKQATYLELQHYMPYTPVLVTSAPDVSPSSISILLYPMSDPDQLGINRQQLK
120

Qy        121 LNLYSYFNDLRHDFKLKVLDARISKNKQNIDTISKYLLELGTYLDGSYRMMEQNTHNINK
180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 LNLYSYFNDLRHDFKLKVLDARISKNKQNIDTISKYLLELGTYLDGSYRMMEQNTHNINK
180

Qy        181 NTHNINKNTHNINKLSKELQTGLANQSALSMLVQPNGVGKTSVSAAVGGYRDKTALAIGV
240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 NTHNINKNTHNINKLSKELQTGLANQSALSMLVQPNGVGKTSVSAAVGGYRDKTALAIGV
240

Qy        241 GSRITDRFTAKAGVAFNTYNGGMSYGASVGYEF 273
              ||||||||||||||||||||||||||||||||
Db        241 GSRITDRFTAKAGVAFNTYNGGMSYGASVGYEF 273
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The invention disclosed in this application lacks novelty, therefore the other claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept. Inasmuch as, the technical feature does not define a contribution over the art, it is not “special” within the meaning of PCT Rule 13.2. Consequently, Groups I-VII lack unity of invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

SEQ ID Nos. 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15 16, 17, 18, 19, 20, 51, or 54.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic 1-6, 8-10, 13-19 and 21-22. These claims correspond to Groups I and III-VII.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they differ structually.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/

Examiner, Art Unit 1645

February 3, 2009